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Spring/Summer 2023 ORP Newsletter

The Office of Research Policy is responsible for providing research compliance support and training to faculty, students and staff in order to comply with federal, state and local regulations as well as Caltech policies. ORP includes Caltech’s Office of Research Compliance, the Office of Export Control, and the Office of Laboratory Animal Resources. Regulatory Committees supported by this office include the IACUC, the IRB, the IBC, and the HESC. ORP also manages Caltech’s Researcher Financial Conflicts of Interest program, Research Integrity, and Controlled Substances.

This newsletter is issued two times a year, highlighting important regulatory changes, changes in institute policy, and upcoming educational events and committee meetings. We hope you find this informative & useful!

Important Grantee Regulatory Updates

Research Integrity Training: Both NSPM-33 and the CHIPS and Science Act of 2022 (P.L. 117-167) (CHIPS Act), require Research Integrity training for all investigators at all career stages. A new training module is being built for faculty and staff researchers. All postdocs and graduate students will continue to be required to complete the CITI RCR training available through ACCESS.Caltech.edu.

Digital Persistent Identifier: The National Science Foundation (NSF) will soon begin crunching several large databases to see whether there are scientists who failed to disclose ties to foreign institutions in their grant applications. All investigators with federal awards should obtain an ORCID (a digital persistent identifier-DPI) to ensure you have a single profile and your information will not be confused with another investigator with the same or similar name. 84% of Caltech faculty already have an ORCID!

Research Security: The Chief Research Policy Officer and the Vice Provost are visiting Division Faculty Meetings to present an overview of current and upcoming Research Security requirements. Please see “Events” for important dates.

The Office of Science and Technology Policy published a Request for Information (RFI) in the Federal Register asking research organizations to comment on the Draft Standard Requirements for Research Security Programs that include Foreign Travel Security, Cybersecurity, and various Training in Research Integrity, Research Security and Export Control requirements. A summary of the rule requirements will be presented in the Faculty/Division meetings. Various university associations are providing comments, including COGR, AAU, Educause, and AUECO.

If you wish to submit comments, comments are due by June 5, 2023.

EVENTS

Faculty/Division Research Security
- GPS – May 11, 2023
- CCE – June 20, 2023
- BBE – May 31, 2023
- EAS – July 6, 2023
- HSS – May 22, 2023
- PMA - TBD

IACUC Meetings
- June 8, 2023
- July 11, 2023
- August 8, 2023
- September 12, 2023
- October 10, 2023
- November 14, 2023
- December 12, 2023

IBC Meetings
- June 6, 2023
- July 2023 TBD
- August 2023 TBD
- September 5, 2023
- October 3, 2023
- November 7, 2023
- December 5, 2023

IRB Meetings
- July 14, 2023
- September 8, 2023
- November 3, 2023

HESC Meetings
- Fall 2023 TBD
Conflict of Interest Updates

Annual COI Disclosure Period: Caltech’s annual Disclosure of Financial Interests and Commitments (DFIC) submission period begins on June 1, 2023, and runs through July 31, 2023. Please note that beginning August 1, 2023, all individuals who have not submitted their annual disclosure will be restricted from submitting sponsored research proposals.

During the annual disclosure process, we request that you disclose all outside commitments, activities, and when applicable, financial interests that are or may be perceived to be related to your institutional responsibilities. An outside commitment is related to your institutional responsibilities when the Entity’s activities or products (e.g., physical or service) broadly relate to your field of research, teaching activity, or administrative responsibility.

Foreign Talent Recruitment Programs: This is an important reminder to upload copies of agreements with foreign entities if you have appointments, collaboration agreements, or are otherwise providing consulting or research services. Foreign agreements will be reviewed to identify whether they are foreign recruitment programs (FTRP). Beginning next year, any person participating in a Malign FTRP will be precluded from proposing for or receiving US federal funding. See FTRP Website for details.

DFIC System Updates: In preparation for this year’s annual DFIC submission period, our system received multiple updates to remove compliance-related barriers. An updated user guide can be found here. These updates include a new travel portal that allows users the ability to associate travel with a previously disclosed entity and revised questions in an effort to provide clarity and background to system users. We believe these changes highlight Caltech’s commitment to ensuring outside commitments and conflicts of interest are reviewed and managed in a manner that will instill public confidence in our research community.

Biosketch and Other Support: This is a reminder to ensure that you are disclosing your professional appointments and commitments (Biosketch) as well as your other support (aka current and pending support) in accordance with federal requirements. The guidance documents for disclosure can be found here: NSF, and NIH.

New COI Manager: The campus welcomed Mel Dereje as our new Conflict of Interest manager as of February 2023. Mel comes to us with a wealth of experience as a COI administrator from Georgetown University and Johns Hopkins University.

Export Compliance Regulatory Updates

Protection of Human Rights Worldwide: In March 2023, the Bureau of Industry and Security (BIS) amended the regulations to explicitly confirm that U.S. "foreign policy interest of protecting human rights worldwide is a basis for adding entities to the Entity List." This change expands BIS’s scope of reasons why an entity can be designated as a prohibited party. (Prohibited parties are subject to stricter export controls, prohibitions and transfer of items including low-level technologies and items are subject to government approval prior to transfer to a foreign party.)

Iranian Unmanned Aerial Vehicles and Their Use by the Russian Federation Against Ukraine (Effective Date: 2/24/2023): New export regulations address the use of Iranian Unmanned Aerial Vehicles or Systems (UAVs) by Russia in its ongoing war against Ukraine, contrary to U.S. national security and foreign policy interests. The regulatory amendments target Iran’s supply of UAVs to Russia to enhance Russia’s defense industrial base and its military efforts against Ukraine. The rule also imposes license requirements for EAR99 items (low-level items) that are destined to Iran, and it aligns with the existing Russia/Belarus rules to ensure items are similarly controlled. Federal Register 88 FR 12150

Export Compliance Liaison Committee: The committee meets quarterly to address new and existing rules and regulations that change frequently due to foreign policy, national security issues and address their impact on fundamental research—the freedom to publish and disseminate our research results. We also invite interesting subject matter experts to attend as guest speakers.

Export Control Basics Corner:
Export controls are the rules that govern:

- The export, reexport, and transfer by U.S. and foreign persons
- Of commodities, technology, software, and services
- To destinations, end-uses, and end-users
To accomplish various national security and foreign policy objectives.
Visit us!  https://researchcompliance.caltech.edu/export

IBC Updates

New Chair: We would like to thank our longtime chair, Dr. Jared Leadbetter, for all his years of dedication and service to the IBC Committee. Dr. Leadbetter’s guidance and insight have been essential for ensuring the Institute’s compliance with the NIH Guidelines and the U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. His leadership and input in committee matters will be missed.

The IBC thanks Dr. Rustem Ismagilov for graciously stepping in to be interim chair. Dr. Ismagilov was most recently the vice chair and continues to provide valuable insight and thoughtful input in the committee. We are grateful to him for taking on this new leadership role.

New Administrator: The IBC welcomed Tiffani Cheung as our new administrator as of April 2023. Tiffani replaces Amy Chang who has become our new IACUC Administrator.

IRB Updates

Protocol Application System (PAS): IRB PAS was successfully implemented in January. The IRB PAS User Guide can be found on the IRB website and will soon have a direct link within the system. Please contact irb@caltech.edu to schedule an orientation to PAS or with any general questions.

IRB Training Requirements: IRB protocols are classified as social behavioral or biomedical studies, and specific training courses are assigned to the two types of studies: Social & Behavioral Research for social behavioral studies, and Biomedical Research for biomedical studies. The IRB will soon offer a hybrid CITI course that will cover both biomedical and social behavioral topics. This course will be available for researchers whose labs participate in both types of research and for protocols that might be a social behavioral study that involve the use of drugs or device, radiation, and radiolabeled tracer, and other invasive procedures (e.g., fMRI, electrical stimulation).

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<tr>
<th>Protocol Designation</th>
<th>Acceptable CITI Training Course</th>
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<tr>
<td>Social Behavioral Protocol</td>
<td>Social &amp; Behavioral Research – Basic/Refresher</td>
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<td>Hybrid SBR/BIO Research – Basic/Refresher</td>
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<td>Biomedical Protocol</td>
<td>Biomedical Research – Basic/Refresher</td>
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<tr>
<td></td>
<td>Hybrid SBR/BIO Research – Basic/Refresher</td>
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The proposed changes were approved at the May IRB meeting (5/19). All updates will be communicated to researchers soon.

IACUC and OLAR Updates

New Administrator: The IACUC welcomed Amy Chang as our new administrator in January of this year. Amy brings a wealth of experience to this role, having recently served as the administrator for the IBC and previously the Office Manager for OLAR for many years.

AAALAC Accreditation: During October-November 2023, we will renew our AAALAC Accreditation. AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. The AAALAC accreditation process is a comprehensive evaluation of our animal care and use program and provides many benefits to the campus. Benefits of Accreditation - AAALAC You will receive more information as our scheduled site visit approaches, sometime in October – November 2023.

New OLAR Recharge Rates: The Institute implemented new per diem and service rates as of May 1, 2023. The new rate schedules are available at Per Diem and Recharge Rates | Office of Laboratory Animal Resources (caltech.edu).

Update User Profiles: The Caltech IACUC requests that all individuals ensure that their personnel information is complete in their User Profiles by filling out the Education and Experience sections in the Protocol Application System. This is required in preparation for the AAALAC re-accreditation process in fall 2023.
Training Requirements Reminder: Please be reminded that individual animal users are responsible for keeping track of their IACUC training records and completing all required training prior to starting work listed in the IACUC protocol. Your training profile, including a summary of incomplete training, is available in your profile in the Protocol Application System. We recommend checking your profile to confirm your training status.

IACUC Standard Operating Procedures: IACUC SOPs can be found in the Protocol Application System. For ease of access, the general frequently used SOPs are also now available at: IACUC Standard Operating Procedures | Research Compliance (caltech.edu)